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EXAMINER	
ORWIG, KEVIN S	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,436	YOSHITAKE ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-12 and 14-24* is/are pending in the application.

4a) Of the above claim(s) *25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-12, and 14-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/6/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments and arguments filed Jul. 20, 2009 are acknowledged and have been fully considered. Claims 1, 2, 4-12, 14-26, and 28-30 are now pending. Claims 3, 13, and 27 are cancelled; claims 1, 12, 14, 15, 19, and 21-24 are amended; claims 25-30 are withdrawn. Claims 1, 2, 4-12, and 14-24 are now under consideration.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided or were not provided in English.

OBJECTIONS/REJECTIONS WITHDRAWN

The objection to claim 22 are withdrawn in light of the claim amendments.

The rejection of claims 21-24 under 35 U.S.C. 112, 2nd paragraph is withdrawn, upon further consideration.

The double patenting rejection over 11/543,991 is withdrawn in light of the claim cancellation in the copending case.

OBJECTIONS/REJECTIONS MAINTAINED

The rejection of claims 1-21 under 35 U.S.C. 103(a) over AOKI and NAKAJIMA is maintained as discussed below.

The rejection of claims 1-21 under 35 U.S.C. 103(a) over SAEKI and AOKI is maintained as discussed below.

The double patenting rejections over 10/849,544 and 10/938,554 are maintained in modified form as no action regarding these rejections has been taken by applicants at this time.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-12, and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over AOKI (WO 03/043661; Published May, 30, 2003; 3rd foreign reference on IDS dated Sep. 26, 2006; the corresponding national phase publication U.S. 2005/0163846, reference CR on IDS dated Jul. 25, 2007 is relied upon as an English language equivalent for the rejection set forth herein) in view of NAKAJIMA (JP 2000128779; Published May 9, 2000; last foreign reference on IDS dated Sep. 26, 2006; human translation provided herein).

It is noted that a machine translation was previously provided for Nakajima. A human translation has now been obtained and is relied upon herein as further evidence of Nakajima's teachings.

1. Aoki discloses sustained- or pulsed-release pharmaceutical preparations in the form of tablets or granules of an acid-unstable compound. These compositions comprise a core containing the acid-unstable compound, which is covered with a coating that contains a mixture of a water-insoluble polymer and an enteric polymer (abstract). The core contains a benzimidazole compound, preferably rabeprazole (elected species) (paragraphs [0024], [0036], [0052]; claim 10) and may contain crospovidone as a preferable disintegrant (paragraphs [0054], [0059], and [0060]). Regarding the coating, Aoki discloses embodiments wherein the preferred water-

insoluble polymer is ethyl cellulose (elected species) and the enteric polymer is methacrylic acid/methyl methacrylate copolymer (elected species) (paragraphs [0019] and [0020]). Aoki teaches that the coating further contains a plasticizer including, *inter alia*, triethyl citrate, cetyl alcohol, glycerol fatty acid ester, and propylene glycol (paragraphs [0017] and [0021]). Aoki teaches that the core preferably contains an alkaline substance such as, *inter alia*, sodium and potassium hydroxide (paragraphs [0018] and [0022]). Aoki teaches the use of magnesium stearate (elected species) as a lubricant component of the core but not a component of the coating.

2. However, the use of magnesium stearate in coatings was known in the art at the time of the invention. For example, Nakajima discloses a pharmaceutical preparation comprising a core that includes a drug and a water-swelling substance (paragraph [0019]; claim 1). This core is coated with a film for controlling the release of the drug. The film may contain ethyl cellulose, an enteric polymer, and a water-insoluble substance (paragraphs [0019], [0020], and [0029]). Nakajima teaches that the time from administration of the medication to initial release of the drug (lag time) can be controlled with good reliability by adjusting the type and amount of the water-insoluble substance contained in the film for controlling the release of the drug (paragraphs [0061], [0070]; claim 1). The water-insoluble substance may advantageously be magnesium stearate (paragraph [0031]; claim 2). Thus, one of ordinary skill would have been motivated to use magnesium stearate in the coating taught by Aoki to help adjust the lag time of the controlled-release compositions as taught by Nakajima.

3. Aoki teaches that the water-insoluble polymer is present in an amount from 20-80%, preferably from 25-75% by weight relative to the weight of the water-insoluble polymer and the enteric polymer (pars. [0016] and [0078]) (reading on claim 14). Nakajima teaches the use of the water-insoluble substance from 75-1500 parts by weight relative to 100 parts by weight of ethylcellulose (paragraph [0028]; claim 1). Furthermore, Nakajima teaches adjusting the amount of water-insoluble substance in the coating (paragraph [0070]). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to optimize the amount of water-insoluble substance (i.e. the hydrophobic wax). One would have been motivated to do so to modify the lag time of the controlled-release composition as taught by Nakajima. Thus, through no more than routine experimentation, a skilled artisan would add magnesium stearate to the coatings of Aoki, following the teachings of Nakajima regarding the amount of hydrophobic wax relative to ethyl cellulose, and arrive at the amount of magnesium stearate instantly claimed. For instance, if one were to use, for example, 30% ethyl cellulose (a preferred amount as taught by Aoki), one would be motivated to add 30% magnesium stearate per the teachings of Nakajima, reading on the instantly claimed amount relative to the total of the coating. Claims 1-3, 5-12, 14, and 16-20 are obvious over Aoki and Nakajima.

4. Aoki teaches the use of an inert intermediate coating between the core and the enteric coating to separate the somewhat acidic enteric coating from the core (paragraph [0068]), rendering claim 4 obvious.

5. Aoki teaches amounts of the plasticizer from 0.5-8% (depending on ethanol content) by weight relative to the total weight of the coating (Example 1), rendering claim 15 obvious.

6. Regarding claim 21, both Aoki and Nakajima teach the formulation of their compositions as capsules (see Aoki, paragraph [0048]; and Nakajima, paragraphs [0022], [0039], and [0040]; claims 6-12).

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue the amount of talc in Aoki's examples is outside the claimed range for the magnesium stearate hydrophobic wax (response, p. 9). Applicants argue that Nakajima does not teach a core with an alkaline additive and does not teach an enteric polymer in the coating (response, p. 10). Applicants argue that the prior Office Action provides no evidence that Nakajima's coating would function with the instantly claimed core (response, p. 10).

At the outset, applicants are reminded that a reference is not limited to the disclosed examples. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Applicants are also reminded that the instant rejection was based on a combination of references. In response to applicants' arguments against the references individually, one cannot show

nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In this case, Aoki teaches the use of an alkaline additive in the core and teaches the use of both ethyl cellulose (elected species) and an enteric polymer (e.g. methacrylic acid/methyl methacrylate copolymer (elected species) (paragraphs [0019] and [0020]). Nakajima provides explicit motivation for one to add the hydrophobic wax magnesium stearate to the coating compositions of Aoki:

> "It can be seen that it is possible to adjust the length of the lag time by changing not only the coating film thickness, but also the percentage of the water insoluble powdered material added." (par. [0061])

Thus, not only does Nakajima provide motivation to add magnesium stearate to the coating of Aoki, the above passage, in addition to Nakajima at paragraph [0070], proves that applicants are incorrect in their assertion that Nakajima does not recognize the significance of the amount of hydrophobic wax (i.e. the hydrophobic powdered material) in the coating. Furthermore, Nakajima allows for the addition of enteric polymers to the magnesium stearate/ethyl cellulose coating (see par. [0029]). Thus, in light of Aoki and the direct teachings of Nakajima, applicants assertion that an artisan would not have expected success in using Nakajima's coating is without merit. It is also noted that applicants have provided no evidence to support their assertion that an artisan would not have had a reasonable expectation of success. The MPEP states, "Obviousness does not require absolute predictability, however, at least some degree of predictability is required." See MPEP § 2143.02(II). In this case, since Nakajima

directly teaches controlling lag time by adjusting the amount of hydrophobic wax, the skilled artisan would only have expected success in adding a hydrophobic wax to Aoki's coatings.

It is further noted that, no evidence of criticality has been presented for the claimed percentage range for the hydrophobic wax component. Applicants are reminded of the teachings in their own specification. For instance, see paragraph [0049], which states:

> "There are no particular limitations on the amount of the hydrophobic wax in the release-controlling coating, but this amount is generally 5 to 65 wt %, preferably 8 to 50 wt %, more preferably 10 to 35 wt %, particularly preferably 20 to 35 wt %, based on the weight of the release-controlling coating."

Thus, it is clear that the instantly claimed range is not critical, but merely preferred.

Applicants argue that there is not teaching or suggestion of solving the problem of lag time in Aoki and assert that Aoki does not recognize the hydrophobic wax as a result effective variable (response, p. 10).

Again, applicants are reminded that the instant rejection was based on a combination of references. In response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Nakajima not only teaches the instantly claimed solution to the instantly claimed problem, but clearly recognizes the hydrophobic wax as a result effective variable. Applicants are merely combining prior art elements according to

known methods to yield no more than predictable results.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki (as evidenced by U.S. 2005/0163846) in view of Nakajima as applied to claims 1-21 above, and further in view of WHITTLE (U.S. 6,444,689; Issued Sep. 3, 2002).

7. The teachings of Aoki and Nakajima are presented *supra*. Aoki and Nakajima are silent to the packaging of their compositions. Nonetheless, one of ordinary skill in the art would have known to package the compositions for convenience and storage as is customary in the art.

8. For example, Whittle discloses pharmaceutical preparations of benzimidazole compounds as enterically coated tablets, capsules, or sachets (col. 44, lines 37-40). Whittle teaches that packaging the final dosage form is desirable for long term stability of the dosage form since a desiccant can be added to the package to reduce the water content of the preparation (col. 44, lines 41-49). Thus, claims 22-24 would be obvious to an ordinary artisan in light of Aoki, Nakajima, and Whittle.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Whittle does not remedy the alleged deficiencies of Aoki and Nakajima (response, p. 11).

As discussed *supra*, Aoki and Nakajima together teach or suggest each element of the instant claims and therefore render the claims obvious. The discussion of Aoki

and Nakajima is incorporated herein. No other arguments were made with respect to Whittle. Thus, the combination of Aoki, Nakajima, and Whittle is properly maintained.

Claims 1, 2, 4-12, and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over SAEKI (U.S. 5,035,899; Issued Jul. 30, 1991; Reference AR on IDS dated Oct. 17, 2007) in view of Aoki.

1. Saeki discloses pharmaceutical preparations, including tablets and capsules, of an acid-unstable compound comprising a core containing the acid-unstable compound, which is coated with a hardly water-soluble film forming material, a hardly water-soluble substance, and an enteric film (abstract). The acid-unstable compound is a benzimidazole compound, most preferably rabeprazole (elected species) (abstract; col. 2, lines 16-18; claims 1, 3, and 5). Saeki discloses embodiments wherein the hardly water-soluble film forming material is ethyl cellulose (preferably at least 10%) (elected species) (col. 2, lines 46-48), the hardly water-soluble substance is magnesium stearate (elected species) (col. 2, lines 42-43; claim 1), and the enteric film is methacrylic acid/methyl methacrylate copolymer (elected species) (col. 3, lines 12-15). The water-insoluble polymer is approximately 50% of the total weight of the water-insoluble polymer and the enteric polymer (col. 2, lines 45-48, as well as the examples, wherein Saeki gives weights and teaches the water-insoluble and enteric coatings weigh approximately 10 mg each). Instant Claim 5 is obvious over Saeki because the ability to be used for pulsed-release is inherent to the structure, which is directly taught by Saeki. Saeki teaches an alkaline substance (magnesium oxide) (table in example 1) and a plasticizer (col. 8, lines 14-16). Thus, Saeki discloses each element of the instantly

claimed composition except for the inclusion of a disintegrant in the core. However, the use of disintegrants in similar pharmaceutical preparations was well-known at the time of the invention.

2. For example, Aoki discloses preparations that are substantially identical to those instantly claimed (see discussion *supra*). Aoki teaches that the use of disintegrants together with an alkaline substance will contribute to better stabilization of the benzimidazole-based compound. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include a disintegrant in the core of Saeki's compositions together with an alkaline additive, to provide a more stable benzimidazole preparation per Aoki's teachings. In combination, Saeki and Aoki render the instant claims obvious.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Saeki is silent as to the use of a release-controlling coating comprising the three ingredients instantly claimed (response, p. 11).

This argument is unpersuasive because Saeki teaches all of the features instantly claimed. Applicant is apparently arguing the intended use of the composition, which does not carry patentable weight. Moreover, in response to applicants' argument that Saeki does not recognize the instantly claimed use (i.e. to control lag time), the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd.

Pat. App. & Inter. 1985).

Applicants argue unexpected results (response, p. 11).

Applicants have provided no evidence to support their assertion of unexpected results. Moreover, Nakajima explicitly recognizes the alleged unexpected result and Saeki teaches it as well (see Saeki at col. 2, lines 45-56). Thus, it is clear that in view of the totality of the art, a skilled artisan would have expected the very predictable result that applicants allege to be unexpected. Also, Saeki also stipulates a lower amount of the hardly water-soluble fine material (e.g. magnesium stearate), but not an upper limit (see Saeki at col. 2, lines 54-56). Thus, the skilled artisan would expect to optimize the amount of the hydrophobic wax component through routine methods. Furthermore, no evidence of criticality has been presented for the claimed percentage range (see discussion above under response to arguments relating to Aoki and Nakajima).

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki (as evidenced by U.S. 2005/0163846) in view of Nakajima as applied to claims 1-21 above, and further in view of CHEN (U.S. 2002/0045184; Published Apr. 18, 2002).

3. The teachings of Saeki and Aoki are presented *supra*. Saeki and Aoki are silent to the packaging of their compositions. Nonetheless, one of ordinary skill in the art would have known to package the compositions for convenience and storage as is customary in the art.

4. For example, Chen discloses packages for dispensing proton pump inhibitors (abstract). The packaging includes a blister card (i.e. a blister pack), each blister of

which may comprise a unit dosage form (e.g. a tablet or capsule) of a proton pump inhibiting drug (paragraphs [0008], [0042]). Chen teaches that the packaging is advantageous for easy distribution and administration (paragraph [0005]). Thus, claims 22-24 would be obvious to an ordinary artisan in light of Saeki, Aoki, and Chen.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Chen does not remedy the alleged deficiencies of Aoki and Nakajima (response, p. 11).

As discussed *supra*, Aoki and Nakajima together teach or suggest each element of the instant claims and therefore render the claims obvious. The discussion of Aoki and Nakajima is incorporated herein. No other arguments were made with respect to Chen. Thus, the combination of Aoki, Nakajima, and Chen is properly maintained.

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious

to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent No. 10/849,544

Claims 1, 2, 4-12, and 14-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, and 10-12 of copending Application No. 10/849,544 in view of Aoki and Nakajima. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '544 claims renders obvious that of the instant claims. The difference between the two claim sets is that the instant claims recite the inclusion of a disintegrant (claim 1) and an alkaline substance (claim 3) in the pharmaceutical preparation. However, these elements, and thus the entire scope of the instant claims is rendered obvious since, by the reasoning presented in the rejections *supra*, the use of a disintegrant, an alkaline substance, and the instantly claimed weight

percentages of all the components are obvious variations based on the prior art. Additionally, the open language in the '544 claims allows such components.

Claims 1-20 directed to an invention not patentably distinct from claims 1-3, 7, and 10-12 of commonly assigned 10/849,544. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/849,544, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

U.S. Patent No. 10/938,554

Claims 1, 2, 4-12, and 14-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 41-43, and 45-55 of copending Application No. 10/938,554 in view of Aoki and Nakajima. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '554 claims renders obvious that of the instant claims. The difference between the two claim sets is that the '554 claims recite the inclusion of mannitol and the instant claims recite the inclusion of a disintegrant (claim 1) and an alkaline substance (claim 3) in the pharmaceutical preparation. However, these elements, and thus the entire scope of the instant claims is rendered obvious over the prior art. It is noted that Aoki teaches the use of an inert intermediate coating and teaches mannitol as a suitable inert material. By the reasoning presented in the rejections *supra*, the use of a disintegrant, an alkaline substance, and the instantly claimed weight percentages of all the components are obvious variations based on the prior art.

Claims 1-20 directed to an invention not patentably distinct from claims 41-43, and 45-55 of commonly assigned 10/938,554. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/938,554, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were

commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the double patenting rejections should be withdrawn because of alleged deficiencies in the combination of Aoki and Nakajima (response, p. 13).

As discussed *supra*, Aoki and Nakajima together teach or suggest each element of the instant claims and therefore render the claims obvious. The discussion of Aoki and Nakajima is incorporated herein. The double patenting rejections are maintained.

NEW GROUNDS OF OBJECTION/REJECTION

Summary/Conclusion

Claims 1, 2, 4-12, and 14-24 are rejected; claims 3, 13, and 27 are cancelled.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin S Orwig/

/David J Blanchard/
Primary Examiner, Art Unit 1643